

**Prospective observational study of the impact of vaginal surgery (pelvic organ prolapse with or without urinary incontinence) on female sexual function**

Tyagi, Veenu; Perera, Mahesh; Guerrero, Karen; Hagen, Suzanne; Pringle, Stewart

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1 Prospective Observational study of the impact of vaginal surgery (Pelvic Organ  
2 Prolapse +/- Urinary Incontinence) on female sexual function.

3 **Authors:**

4 **Veenu Tyagi (MRCOG)**

5 Consultant subspecialist Urogynaecologist,

6 NHS Greater Glasgow and Clyde,

7 Queen Elizabeth University Hospital , 1345 Govan Road, Glasgow, G51 4TF

8 [Veenu.Tyagi@ggc.scot.nhs.uk](mailto:Veenu.Tyagi@ggc.scot.nhs.uk)

9 0044 1412012820

10

11 **Dr Mahesh Perera (MRCOG),**

12 Consultant Obstetrician and Gynaecologist,

13 NHS Greater Glasgow and Clyde,

14 Princes Royal Maternity Hospital, 16 Alexandra Parade, Glasgow, G16 2ER

15 [Mahesh.Perera@ggc.scot.nhs.uk](mailto:Mahesh.Perera@ggc.scot.nhs.uk)

16 0044 1412115248

17

18 **Dr Karen Guerrero (FRCOG),**

19 Consultant subspecialist Urogynaecologist

20 NHS Greater Glasgow and Clyde

21 Queen Elizabeth University Hospital, 1345 Govan Road, Glasgow, G51 4TF

22 Karen. [Guerrero@ggc.scot.nhs.uk](mailto:Guerrero@ggc.scot.nhs.uk)

23 0044 1412012820

24

25 **Professor Suzanne Hagen (PhD CStat CSci)**

26 Interventions Programme Director

27 Nursing, Midwifery and Allied Health Professions Research Unit

28 Cowcaddens Road, Glasgow G4 0BA

29 [s.hagen@gcu.ac.uk](mailto:s.hagen@gcu.ac.uk)

30 0044 1413318104

31

32

33 **Dr Stewart Pringle (FRCOG)**

34 Consultant Gynaecologist

35 NHS Greater Glasgow and Clyde

36 Queen Elizabeth University Hospital, 1345 Govan Road, Glasgow, G51 4TF

37 [Stewart.Pringle@ggc.scot.nhs.uk](mailto:Stewart.Pringle@ggc.scot.nhs.uk)

38

39 **Corresponding author: Veenu Tyagi**

40 [Veenu.Tyagi@ggc.scot.nhs.uk](mailto:Veenu.Tyagi@ggc.scot.nhs.uk)

41 0044 1412012820

42

43 **Author's participation with the manuscript:**

44 VT: project design, data collection, data analysis, writing of manuscript

45 MP: data collection, writing of manuscript

46 KG: project design, data collection, data analysis, writing of manuscript

47 SH: Data analysis, writing of manuscript

48 SP: manuscript writing

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50 All the authors have nothing to disclose.

51

52 **Conflict of Interest**

53 The authors declare that they have no conflict of interest.

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56

## **Abstract**

### **Introduction and Hypothesis:**

There is a difference of opinion in the literature as to whether or not pelvic organ prolapse (POP) is a direct cause of FSD. Sexual function in women is negatively impacted by presence of urinary symptoms. Sexual dysfunction(SD) might be improved, unchanged or worsened by pelvic floor surgery.

### **Methods:**

In this study we observed the SD and impact of surgical intervention on female sexual function using validated questionnaire (PISQ-12) in women undergoing pelvic organ prolapse +/- urinary incontinence surgery. 200 women were recruited and followed up 6 and 12 months post operatively.

### **Results:**

Sexual function as measured by the PISQ-12 improved after surgery irrespective of the nature of surgery or the patient's past gynaecology history. Improvement in sexual function was seen by 6 months (97 patients) post-surgery ( $p < 0.05$ ) after which(assessed at 12 months – 80 patients) no further change in PISQ-12 was observed. Improved sexual function was associated with better patient satisfaction post-operatively.

### **Conclusions:**

Sexual function improved after surgery irrespective of nature of surgery and patient past gynaecology history. Our study will help in counselling women with POP and/or UI undergoing surgery about potential improvement in sexual function.

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**Keywords:** Female sexual function, validated questionnaire, vaginal surgery

**Summary:** Majority of women will have improvement in sexual function after prolapse +/- incontinence surgery and this is strongly positively associated with patient satisfaction.

## 98 INTRODUCTION

99 Female Sexual Dysfunction (FSD) is a common problem, with data from the National  
100 Health and Social Life Survey showing that 43% of women aged 18–59 years  
101 experiencing some form of FSD(1). The aetiology of FSD is multifactorial, with  
102 hormonal, psychological, anatomical, vascular and neurogenic elements all being  
103 possible aetiological factors(2).

104 Pelvic Organ Prolapse (POP) and urinary incontinence (UI) form a major health  
105 burden to women affecting 41-65% of women. Large population study suggests that  
106 the prevalence of stage three or four prolapse is in the range of 2-11% (3,4). An  
107 epidemiological study reported UI to affect up to 41% of the women. (5). At least 1 in  
108 3 parous women undergo at least one surgery for these conditions by the age of 80  
109 years (6). Women with POP and /or UI are at higher risk of sexual dysfunction (7, 8,  
110 9,10,11) compared to those without.

111 Traditionally pelvic floor surgeons have assessed the outcome of vaginal repair  
112 surgery by the degree of restoration of normal pelvic anatomy. Increasingly, however  
113 the effect of prolapse surgery upon a woman's sexual function is being used as an  
114 outcome measure of the success of surgical repair (12,13), especially since the  
115 introduction of vaginal mesh repairs for prolapse (14).

116 There is a difference of opinion in the literature however as to whether or not Pelvic  
117 Organ Prolapse (POP) is a direct cause of FSD. It may not be the prolapse itself but  
118 rather the associated coital incontinence that predicts sexual dysfunction. Likewise, it  
119 appears that vaginal anatomy per se is not an independent factor in the aetiology of

FSD: neither vaginal calibre, nor length, nor atrophy, nor menopausal status have a direct influence on the presence of FSD(22).

## **AIMS**

In this study we aimed to assess the incidence of FSD in a group of sexually active women with stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP) awaiting surgical management. The secondary aim was to determine whether vaginal surgery for prolapse or UI leads to alteration in sexual function and to compare SF in subjects undergoing POP or UI surgery alone with POP surgery combined with UI surgery.

## **STUDY POPULATION**

The study was co-ordinated from the Department of Urogynaecology at the South Glasgow University Hospital in their established Urogynaecology and Pelvic Floor Dysfunction Research Unit. All women undergoing any type of POP repair and/ or urinary incontinence surgery were invited to participate in the study. 200 women were recruited through the Urogynaecology clinics across the service over a 12-month period from June 2011 to May 2012. All women gave written informed consent to be involved in the study.

## **FUNDING**

Project was funded by the Department of Urogynaecology, South Glasgow University Hospital.

## **INCLUSION CRITERIA**



1. Women on the waiting list for surgical repair of POP, UI procedure or both, and;
2. Who have been sexually active in the last 6 months and expect to remain so post-operatively, or;

## **EXCLUSION CRITERIA**

1. Women under 18 years of age
2. Women unable to understand information leaflet
3. Women unable to complete the questionnaire

## **DATA COLLECTION**

Patient's demographics and details about their surgical procedure(s) were obtained from the patient's hospital records.

## **METHODOLOGY**

This was a prospective observational study. Ethical approval was obtained from West of Scotland Ethics Committee. Reference number: 10/S0709/69; 16/03/2011.

Women complaining of symptomatic pelvic organ prolapse and/or SUI who were on the waiting list for pelvic prolapse surgery (POP) +/- urinary incontinence (UI) surgery were recruited at preoperative assessment visit or during hospital admission for their procedure. Consenting participants completed the preoperative questionnaire which included primary and secondary outcome measures prior to surgery.

At 6 and 12 months after surgery a further set of questionnaire(baseline questionnaire and a self designed questionnaire appendix 1) was sent to women by

post, along with a stamped addressed envelope, to be completed at home and returned. Women who did not respond within 2 weeks were sent a reminder letter and questionnaire, and then they were contacted by telephone if there was no response after a further 2 weeks.

### **Primary outcome**

Primary Outcome was to assess incidence of sexual dysfunction by condition specific validated quality of life assessment tool Prolapse/urinary incontinence sexual questionnaire short form (PISQ 12) score. (Rogers 2001, 2003)

### **Secondary outcomes**

Secondary outcome was the change in PISQ-12 and International consultation on Incontinence Questionnaire – Vaginal Symptoms (ICIQ-VS) between baseline and 6 and 12 months after surgery. We also assessed urinary incontinence symptom distress and its life impact at 6 and 12 months using urogenital distress inventory short form (UDI-6) and Incontinence Impact Questionnaire IIQ-7. Patient satisfaction with surgery was measured using a study specific , non validated instrument (appendix 1) at 6 and 12 months.

### **Analysis**

We tabulated descriptive statistics, reporting baseline demographics and clinical characteristics with means and SDs, or medians and IQRs as appropriate. A paired t-test was used to compare baseline, 6 month and 12 month scores, and analysis of variance to test for differences between surgery groups and post operative satisfaction levels. Data were analysed in SPSS version 19 and a 5% level of significance was used throughout.

## Results

Two hundred women were recruited of which 180 (90%) returned completed baseline questionnaires. At 6-months 97 (48.5%) patients returned completed questionnaires. 87 (43.5%) questionnaires were returned completed at 12-months (Figure 1).

The mean age of participants was 54.4 years (SD 10.1). All women except 3 were parous with a median parity of 2 (range 0-5). 121 (67.2%) women were post-menopausal out of which 15 (8.3%) were on HRT at the time of their surgery. A significantly higher proportion of women who had surgery for prolapse were menopausal (Chi-square = 9.412, df = 2, P = 0.009). The majority of women who had surgery for POP (98%) had stage II or greater prolapse (Table 1).

Thirty-seven (19.5%) women had POP surgery in the past, of which the majority had conventional prolapse surgery without the use of mesh. Four (2.2 %) patients had surgery using mesh graft and 2 (1.1%) had both conventional and surgery using mesh. Seventeen (9.5%) patients had a previous UI procedure. One hundred and sixteen (68%) patients had no documented urinary symptoms (table 1).

A total of 130 women underwent POP surgery, 29 had UI surgery and 21 women had both POP and UI surgery (Table 2).

## Sexual function

Overall the mean baseline PISQ-12 score in our study population was 30.54 (SD 6.55). There was no statistical difference in baseline PISQ-12 in women as per their age, parity, menopausal status or whether they had previous POP and /or UI surgery(table 3). There was also no statistically significant difference in the baseline

PISQ-12 between groups of women awaiting only POP surgery or only UI surgery or both POP and UI surgery (Table 4).

For all women the mean PISQ-12 score increased (improved) to 33.4 (SD 7.36) at 6 months and 33.5 (SD 7.40) at 12 months (Table 3). The improvement in PISQ-12 score from baseline to 6 and 12 months was statistically significant (Table 3) but not from 6 months to 12 months. The improvement in PISQ-12 was not significantly different between the groups of women having POP surgery, UI surgery or both POP and UI surgery (ANOVA  $F=2.266$ ,  $df=2$ ,  $p=0.109$ ). It was also not influenced by any of the above mentioned demographic characteristics.

Improvements in UDI-6, VS and IIQ-7 scores from baseline to 6 months were statistically significant but not from 6 to 12 months, similar to PISQ-12 scores (Table 4).

No significant difference was seen between surgery types (no mesh, vaginal mesh for prolapse, mesh for UI, abdominal mesh for prolapse) in the change in PISQ-12 score from baseline to 6 months (ANOVA  $F = 1.463$ ,  $df=3$ ,  $p=0.230$ ), specifically there was no difference between women having prolapse surgery with and without mesh (mean difference -0.99, standard error 1.49,  $p=0.510$ ).

## **Other outcomes**

Improvement in UDI-6 and IIQ-7 scores from baseline to 6 months was significantly different between the three surgery groups (ANOVA  $F = 15.9$ ,  $df = 2$ ,  $P<0.005$  and  $F = 17.9$ ,  $df = 2$ ,  $p < 0.005$  respectively). There was significantly more improvement in both UDI and IIQ scores for those women who had prolapse surgery alone compared to those women who had UI surgery only or those who had combined UI

and prolapse surgery. Improvement in VS scores from baseline to 6 months was not significantly different between groups (ANOVA  $F = 1.757$ ,  $df = 2$ ,  $p = 0.178$ ).

### **Relationship with patient satisfaction**

Seventy-seven (83%) women at 6 months and 60 (78%) women at 1 year reported being either satisfied or very satisfied with their surgical outcome. Being satisfied with surgery at 6 months (not satisfied / satisfied / very satisfied) was significantly associated with improvement in PISQ-12 score from baseline to 6-months (ANOVA  $F=5.915$ ,  $df =2$ ,  $p=0.004$ ).

Improvements in UDI-6 (ANOVA  $F= 4.293$ ,  $df =2$ ,  $p=0.017$ ) and VS scores (ANOVA  $F= 3.771$ ,  $df = 2$ ,  $p=0.025$ ) at 6 months from baseline were also statistically significantly associated with patient satisfaction, however improvement in IIQ-7 was not (ANOVA  $F = 1.618$ ,  $df = 2$ ,  $p = 0.204$ ).

### **Discussion**

Surgery for prolapse has a role in reconstructing the local anatomy and alleviating some symptoms but does not necessarily ensure optimal sexual function. Sexual function might be improved (15, 16, 17), remains unchanged (8, 18) or worsened (19) after repair. Improvement in sexual function could also be due to emotional amelioration due to the cessation of incontinence (20, 21).

Most papers however only report on sexual function as a secondary finding. Most are retrospective in nature, and only a few have involved the use of a validated sexual function questionnaire (22). The prospective studies are either small with 3- 6 months follow up (8) or have used non condition specific questionnaires. **Our study**

255 has large numbers with 1-year follow-up and we have used a validated condition  
256 specific SF questionnaire with SF as the primary outcome.

257 Previously several retrospective and prospective studies have used either non  
258 validated SF questionnaires (8, 17) or self designed questionnaire or telephonic  
259 conversation. Recently condition specific validated sexual health questionnaires  
260 have been developed. At start of this trial the PISQ-31(Pelvic organ prolapse  
261 /Urinary incontinence Sexual Function Questionnaire) (including the short form  
262 PISQ-12) was the only validated condition specific (prolapse and UI) female sexual  
263 function questionnaire available. Other validated condition specific questionnaire that  
264 have been used to assess sexual function following pelvic floor surgery (e.g. Kings  
265 Health Questionnaire, ICIQ-VS) are quality of life questionnaires which include few  
266 questions addressing SF, they really deal with the overall impact of POP and/or UI  
267 surgery on the patients QoL. We therefore chose to use (the short form) PISQ-12  
268 questionnaire for our study. However, we appreciate that this questionnaire only  
269 discriminates between women with and with out sexual dysfunction within the group  
270 of women with POP and UI and may not be optimal to detect SD following treatment  
271 as also concluded by Roos et al 2014 (23). We also understand that PISQ  
272 represents the positive effects of surgery well but does not reflect the possible  
273 negative effects of surgery on sexual function (16).

274 In our study population the mean PISQ-12 score was 30.54 (SD 6.55) with the  
275 maximum possible score of 48. Although a range of score for this instrument (PISQ  
276 12) has not yet been established to classify severity of sexual dysfunction, we  
277 believe that our findings indicate that women enrolled in our study displayed a  
278 significant decrement in SF before POP and/or UI surgery. This observation is

279 consistent with several prior studies that found reduced SF in women with UI and/or  
280 POP or both (24,25,26).

281 The baseline PISQ-12 appears to be comparable to that reported by Brubaker in  
282 SISTEr Trial 2009 (mean 30.54) but lower than that reported by Glavind et al (mean  
283 35.3) (27). This might be due to different baseline characteristics or different  
284 population.

285 We found statistically significant improvement in PISQ 12 score from baseline  
286 (30.54) to 6 months (33.45). Other studies which have reported statistical significant  
287 improvement in the score from baseline either have much smaller number of patients  
288 and shorter follow up.

289 In two different prospective study by Glavind et al (27) with short term follow up after  
290 prolapse surgery (n=81) reported baseline PISQ12 of 35.2 with postop improvement  
291 with positive difference of 3.0 (SD 3.8). Brubaker also reported significant  
292 improvement in PISQ-12 scores from 31.6 (SD 6.85) to 36.85 (SD 5.89). In a long  
293 term study by Lindquist et al where 63 patients after tension free vaginal tapes were  
294 followed for 4 years (n=44 ) used PISQ12 and quoted baseline mean PISQ12 of 33.8  
295 which improved postoperatively(28).

296 Another prospective study by Thakar et al (16), in which 46 women were followed for  
297 4 months post surgery showed significant improvement in SF after surgery for POP  
298 and UI at 4 months. Srikrishna et al (17) recruited 52 sexually active women and  
299 followed them up for 2 years using the GRISS and KHQ questionnaires, concluding  
300 that SF improved following surgery for POP with or out UI procedure. The results of  
301 the above two studies are not comparable as they used different questionnaires.

In a study by Paul et al (8) where 51 patients followed for 6 months, found that SF as measured by FSFI and sexual frequency were unchanged following vaginal surgery for pelvic organ prolapse with or without UI surgery, despite improvement in the stage of prolapse and incontinence symptoms. Weber et al 2005 reported that SF and satisfaction improved or did not change in most women after surgery for prolapse and /or UI. Rogers et al (15) reported mixed results with improved SF in 68 % of women and worsened function in 32% using 2 validated, condition specific questionnaire (PISQ-12 and IIQ-7) preoperatively and 3 and 6 months after surgery in 102 women with a mean age of 47 years. Similar to our study they observed no differences in the total SF scores between women who underwent POP and UI surgery and those who had only UI or only POP surgery.

We found statistically significant improvement in PISQ-12 score from baseline to 6 months with a positive score of 2.91. The minimum clinically important difference for the PISQ-12 is not yet determined. We observed positive improvement in SF scores by PISQ-12. Sloan et al proposed that a change of greater than half of the SD of the pre intervention score is a conservative estimate of an effect size that is clinically meaningful when using QOL questionnaires. (29).

We observed no further improvement in PISQ-12 score after 6 months. This suggests that any improvement in SF due to surgery is generally seen within the first 6-months; however the effect does appear to be maintained up to 1-year. Other studies using self designed non-validated questionnaire or much smaller numbers (15) have shown stability in SF outcomes over follow up period. We therefore suggest following this and our findings that assessment at 6 or 12 months are unlikely to be significantly different and the 6 month follow up can be used for comparison.



327 Success of surgery was defined as patient satisfaction. In our study improvement in  
328 PISQ-12 was observed in women with successful surgery and hence associated with  
329 patient satisfaction postoperatively. This was seen in all three subgroups.  
330 Improvement in SF was strongly influenced by the outcome of surgery i.e. patient  
331 satisfaction. Patient who were satisfied with their surgical outcome reported  
332 improvement in PISQ-12 score compared to those who were not either because of  
333 failure in improvement of symptom or new onset symptom like SUI following POP  
334 surgery. Patient who reported improvement in UDI 6 and VS scores also reported  
335 high satisfaction with their surgical outcome. It may be the presence or absence of  
336 Urinary symptoms rather than surgical technique which defines sexual function (26).

337

338 The numbers in each subgroup of surgery type were too small to make any  
339 comment on whether one technique/surgery improves SF more than the others. In  
340 our study we saw significant improvement in all groups of women with or without  
341 incontinent and hence can conclude that SF improves after surgery not only due to  
342 improvement in UI scores but also due to amelioration in symptoms due to POP.

343 In our study we found significant improvement in UDI and IIQ 7 in the POP only  
344 group where no UI surgery was performed and also significant improvement in VS  
345 score in the UI only group where no prolapse surgery was performed. This may have  
346 contributed to improvement in the PISQ-12 score post operatively in both the POP  
347 only and UI only groups (27). In a cohort of 1267 sexually active women Tok et al  
348 (30) found that women with prolapse had lower SF scores than those without the  
349 POP due to fear of UI during intercourse and also avoidance of sexual intercourse  
350 due to POP. It is therefore understandable that correcting the POP and improving

351 the body image and ameliorating the symptoms should lead to improvement in the  
352 SF.

353 We found improvement in PISQ-12 post operatively irrespective of technique or type  
354 of surgery performed for UI. Improvement in UI scores/symptoms was associated  
355 with patient satisfaction. Whilst our cohort size may have been too small to look for  
356 differences in surgical techniques, our findings are consistent with other authors.  
357 Brubaker 2009(26) (SISTER trial) concluded SF improves after successful surgery for  
358 UI and was irrespective of type/technique of UI surgery and also stage of pop or  
359 with/out concomitant POP surgery.

360 Our study has lots of strength. It is a prospective study with a large number of  
361 patients. We have used a disease specific validated questionnaire PISQ-12. We  
362 have followed up our patients for 1 year postoperatively and have used multiple  
363 validated indices of bladder, POP and sexual function

364 We acknowledge the limitations to our study. There is no normative data for PISQ-12  
365 established and questionnaire only demonstrates the effect of intervention (10). As  
366 this is only an observational study it is not possible to have a definite conclusion that  
367 it was the intervention that led to improvement. Degree of distress cannot be  
368 established as condition specific questionnaire measuring distress is not available at  
369 present (16). Sexual questionnaire IUGA Revised (PISQ-12 R) was not used as this  
370 was not available at the time when study was performed

371 The presence of POP and /or UI rather than severity of the problem or subtype of  
372 POP may impact SF. We did not do any objective follow up for prolapse so are  
373 unable to comment if improvement in sexual function as reported by patients is due  
374 to functional improvement rather than secondary to objective improvement in UI and

/or POP (31). Srikrishna et al (17) objectively assess women at follow up and found that the women with better supported pelvic floor were less likely to have sexual dysfunction.

We however instead used validated IIQ7 and VS questionnaires which evaluate the impact of POP and UI on social function. This may not exactly represent objective evidence of cure of UI and POP however, they do assess in a standardised and validated way the patient's overall improvement and perception of success of surgery. Thus IIQ7 and VS scores are relevant to study for sexual function after treatment of UI and or POP and are representative of successful treatment of POP and or UI surgery (15).

We also acknowledge that there were women who did not complete the forms at recruitment and follow up as they found it too embarrassing. However, our remaining cohort still gives us a larger sample than other reported studies.

## **Conclusion**

Sexual function improves after surgery for POP and UI in the majority of patients. This improvement is strongly positively associated with patient satisfaction with the surgery. Improvement is seen by 6 months and tends to be maintained at 1-year.

Our study will help in counselling women with POP and/or UI undergoing surgery about potential improvement in SF.

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512 Appendix 1



## PATIENT SATISFACTION QUESTIONNAIRE

1. How satisfied are you with your surgery?

- Not satisfied
- Equivocal
- Satisfied
- Very satisfied

2. Have you had any postoperative complications since you have been discharged?

- Infection
- Bleeding requiring hospital attendance/admission
- Mesh erosion
- Others

3. How much do you think your symptoms have resolved?

1      2      3      4      5      6      7      8      9      10  
Not resolved      completely resolved

4. Have you needed any further surgery for your symptoms?

- No
- Yes .....please specify.....

5. What surgery and when did you get the repeat surgery?

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Thanks for your time and help

Urogynaecology Unit  
Greater Glasgow and Clyde

